

Notice of Allowability

Application No.

09/957,483

Examiner

Kathleen M Kerr

Applicant(s)

ARSLANIAN ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/27/04.
2. ☒ The allowed claim(s) is/are 66-72.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____



Kathleen M Kerr
Primary Examiner
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DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final Office action (mailed on March 26, 2004), Applicants filed a response and amendment received on September 27, 2004. Said amendment cancelled Claims 40 and 48-65 and added new Claims 66-72. Thus, Claims 1-39, 42-47, and 66-72 are pending in the instant Office action.

Election

2. New claims 66-72 are drawn to the elected invention. Claims 1-39 and 42-47 remain withdrawn from consideration as non-elected inventions; Claims 66-72 will be examined herein.

Priority

3. As previously noted, the instant application is granted priority to International Application PCT US01/13793 filed on April 26, 2001. This International Application also claims priority to several U.S. provisional and non-provisional applications; said priority is also granted.

Withdrawn - Objections to the Specification

4. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of the Examiner's amendment below.

5. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicant's amendment.

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6. Previous objection to the specification for being confusing on page 137 is withdrawn by virtue of Applicant's amendment.

7. Previous objection to the amendment filed September 19, 2001 under 35 U.S.C. § 132 because it introduces new matter into the disclosure is withdrawn by virtue of Applicant's amendment.

Withdrawn - Objections to the Claims

8. Previous objection to Claim 63 for a typographical error is withdrawn by virtue of Applicant's cancellation of said claim.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

9. Previous rejection of Claims 49, 50, 62, and 65 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "about" is withdrawn by virtue of Applicant's cancellation of said claim and its not being included in the newly filed claims.

10. Previous rejection of Claim 50 under 35 U.S.C. § 112, second paragraph, as being indefinite for referring to "said resin" is withdrawn by virtue of Applicant's amendment removing such claim language from the pending claims.

11. Previous rejection of Claim 52 under 35 U.S.C. § 112, second paragraph, as being indefinite for being unclear as to whether epothilone D is the only epothilone produced in the claimed method is withdrawn by virtue of Applicant's cancellation of said claim.

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12. Previous rejection of Claim 65 under 35 U.S.C. § 112, second paragraph, as being indefinite for the metes and bounds of “exogenous trace element solution” is withdrawn by virtue of Applicant’s amendment removing such claim language from the pending claims.

13. Previous rejection of Claims 49 and 65 are rejected under 35 U.S.C. § 112, first paragraph, new matter, is withdrawn by virtue of Applicant’s cancellation of said claims.

14. Previous rejection of Claims 40, 48-59, and 62-65 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicant’s cancellation of said claims and by virtue of Applicant’s amendment removing such claim language from the pending claims. The pending claims are drawn to using specifically XAD-type resins.

15. Previous rejection of Claim 52 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant’s cancellation of said claim. The instant claims do not require 100% purification of epothilone D.

16. Previous rejection of Claim 54 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant’s cancellation of said claim. Moreover, claims that include methyl oleate as a carbon source are limited to *M. xanthus* cells in the newly pending claims.

17. Previous rejection of Claim 59 under 35 U.S.C. § 112, first paragraph, enabling deposit, is withdrawn by virtue of Applicant’s cancellation of said claim.

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18. Previous rejection of Claim 65 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, is withdrawn by virtue of Applicant's amendment.

Withdrawn - Claim Rejections - 35 U.S.C. § 103

19. Previous rejection of Claims 40, 48, 49, 51, 55, 60, and 61 under 35 U.S.C. § 103(a) as being unpatentable over Hofmann *et al.* (WO 99/42602) in view of Reichenbach *et al.* is withdrawn by virtue of Applicant's amendment. The pending claims are now drawn to either culture *M. xanthus* with methyl oleate as a carbon source; such a step is not taught by this or any prior art. Additionally, other newly pending claims require a crystallization procedure in the methods of obtaining epothilone wherein said procedure (using water as the forcing solvent) is not taught by this or any prior art.

Rejoinder

20. Since the elected Group is drawn to method claims, no claims are subject to rejoinder in the instant application.

EXAMINER'S AMENDMENT

21. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Randolph Ted Apple on December 21, 2004.

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Amendment to the Specification

22. The title is replaced with the following new title:

---Methods of Obtaining Epothilone D Using Crystallization and/or by the Culture of
Cells in the Presence of Methyl Oleate---

23. The claims have been amended as follows:

a) Cancel Claims 1-39 and 42-47.

Conclusion

24. Claims 66-72 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
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December 22, 2004